

WHAT IS CLAIMED IS:

1. An aqueous formulation of human erythropoietin, comprising the human erythropoietin; non-ionic surfactant, polyhydric alcohol, neutral amino acid and sugar alcohol as stabilizers; isotonic reagent; and buffering reagent.

5 2. The aqueous formulation of human erythropoietin according to claim 1, wherein said human erythropoietin is native or recombinant erythropoietin.

3. The aqueous formulation of human erythropoietin according to claim 1, wherein said non-ionic surfactant is a polysorbate-based non-ionic surfactant or poloxamer-based non-ionic surfactant or a combination thereof;

10 said polyhydric alcohol is one or more selected from the group consisting of propylene glycol, polyethylene glycol of a low molecular weight, glycerol and polypropylene glycol of a low molecular weight;

said neutral amino acid is one or more selected from the group consisting of glycine, alanine, leucine and isoleucine.;

15 said sugar alcohol is one or more selected from the group consisting of mannitol, sorbitol, cyclitol and inositol;

said isotonic reagent is one or more selected from the group consisting of sodium chloride, calcium chloride and sodium sulfate; and

20 said buffering reagent is one or more selected from the group consisting of a phosphate buffer and citrate buffer.

4. The aqueous formulation of human erythropoietin according to claim 3,

wherein said non-ionic surfactant is a polysorbate 20, and said polyhydric alcohol is propylene glycol, and said neutral amino acid is glycine, and said sugar alcohol is mannitol, and said isotonic reagent is sodium chloride, and said buffering reagent is the phosphate buffer.

5 5. The aqueous formulation of human erythropoietin according to claim 1, wherein the content of non-ionic surfactant is in the range of 0.0001 to 0.01% (w/v).

6. The aqueous formulation of human erythropoietin according to claim 1, wherein the content of polyhydric alcohol is in the range of 0.001 to 0.1% (w/v).

7. The aqueous formulation of human erythropoietin according to claim 1,
10 wherein the content of neutral amino acid is in the range of 0.001 to 2% (w/v).

8. The aqueous formulation of human erythropoietin according to claim 1, wherein the content of sugar alcohol is in the range of 0.1 to 1.0% (w/v).

9. The aqueous formulation of human erythropoietin according to claim 1, wherein the content of said isotonic reagent is in the range of 0.001 to 0.7% (w/v).

15 10. The aqueous formulation of human erythropoietin according to claim 1, wherein the concentration of salt in the buffering reagent is in the range of 1 mM to 50 mM, and pH thereof is in the range of 6.0 to 7.5

11. The aqueous formulation of human erythropoietin according to claim 1, wherein the content of erythropoietin is in the range of 100 IU/ml to 120,000 IU/ml.